PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

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PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/EP2004/014689	23.12.2004	29.12.2003

International Patent Classification (IPC) or both national classification and IPC
G06F19/00, A61B5/08

Applicant
BOEHRINGER INGELHEIM INTERNATIONAL GMBH

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notifed the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

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Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

   a. type of material:

   ☐ a sequence listing

   ☐ table(s) related to the sequence listing

   b. format of material:

   ☐ in written format

   ☐ in computer readable form

   c. time of filing/furnishing:

   ☐ contained in the international application as filed.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-18
	No:	Claims	
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-18
Industrial applicability (IA)	Yes:	Claims	1-18
	No:	Claims	

2. Citations and explanations

see separate sheet

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (SEPARATE SHEET)

International application No.
PCT/EP2004/014689

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following documents:
D1 = EP 1271384
D2= WO03038727

1. The amendments introduced in this Application, versus the priority document EP03029952 are such that it is considered that the priority is not valid.
The Applicant amended claim 1 in that he included the **disclaimer** that the data used did not include *lung function measurement data*.

As expressed in the Guidelines for Examination at the EPO at C V 2.4, the criteria to determine whether a claim is entitled to the date of priority document is the same criteria as the one used to determine if an amendment satisfies the requirement of Art. 123.2 EPC.
Therefore, to establish if the disclaimer still entitles to the claimed priority, the criteria used in G001/03 for determining if an amendment is allowable with respect to Art. 123.2 EPC will be used:

This disclaimer is viewed as not allowable according to G0001/03 since it establishes novelty versus a very relevant document EP127134, thus this disclaimer does not meet the condition expressed in §2.1 of the headnote of G0001/03 that the anticipation should be accidental.
Further, it is apparent that the disclaimer is introduced in order to substantiate the inventive step, since the aim of the amendment is to render the subject-matter patentable i.e new and inventive versus EP127134 rated as X in the search report and shown anticipating claim 1 in the EESR.
Thus the disclaimer is relevant for assessing the inventive step and not allowable by virtue of §2.3 of the headnote of G0001/03.

2. The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 does not involve an inventive step in the sense of Article 33(3) PCT.

2.1 D1 shows on figure 4 and 9 and diagnostic tool for pulmonary diseases (see claim 1) comprising:
-- a display unit 11 for displaying predefined diagnostic questions relating to the pulmonary disease(see figure 6 step 41, §36, figure 9, column 7, line 19 to 22) and for outputting a diagnostic prognosis on the disease(column 5, line 3 to 5).
-- an input unit 12, figure 4, §36, for a receiving response from a user to the diagnostic questions displayed on the display unit 11,
-- a storage unit for storing (implicit in computer 10) the predefined questions and the interactively input responses,
a calculation unit for
-- assigning each received response a predetermined count value (figure 9, column 7, line 28 to line 35),
-- adding up the count values for obtaining a final count value (column 7 line 35 to 37),
-- assigning the final count value the diagnostic prognosis using a predefined result table stored in the storage unit (column 7 line 37 to 42).

2.2 The only difference between the subject-matter of claim 1 and the disclosure of D1 is the disclaimer specifying that the data used does not include *lung function measurement data*.
This feature may not be viewed as rendering the subject-matter inventive since it is not apparent which problem it solves, as required by Rule 27.1© EPC.

2.3 Should the underlying problem only amount to the suppressing the drawbacks associated with the acquisition of *lung function measurement data*, the attention of the Applicant should then be drawn to the fact that such consideration would not contribute to render the subject-matter inventive, because it is well know in the medical art that, more examinations may provide better or a more precise diagnosis, at the cost of more load on the patient and more costs.

The Art of Diagnostics is always an act of balance between those two constraints, it ends up in a compromise somewhere between the two extremes and is a matter of weighing the *pros* and *contras*, both known to every doctor and not a matter of inventive step. The shear act of omitting a *measurement data* may therefore not substantiate an inventive step.

The subject matter of claim 1 is therefore not viewed as inventive in the sense of Article 33(3) PCT.

2. 4 Should the Applicant non the less consider that the disclaimer was an attempt to claim some inventive subject-matter, it is reminded that *a subject-matter is normally defined in terms of positive features indicating that certain technical elements are present*(Guidelines for Examination at the EPO, CIII 4.12, first sentence).

3. The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 is not new in the sense of Article 33(2) PCT.

D2, shows on claim 1 and figure 1 : a diagnostic tool (expert system) for pulmonary diseases (including COPD and asthma) (page 3, and line 27 to 29, page 5 line 27 to 30) comprising a display unit 3, figure 1, for displaying predefined diagnostic questions relating to pulmonary disease (page 8, line 17 to 18) and for outputting a diagnostic prognosis on the disease (page 8 line 16), and
-- an input unit 4 (page 8, line 22 to 24),
-- a storage unit 2, fig.1 for storing the predefined questions and the interactively input responses (page 8 ,line 15 to 16),
-- a calculation unit 5, figure 1, item 20 for
-- assigning each received response a predetermined count value (page 15, table, line 6, line 8),
-- adding up the count values for obtaining a final count value (cf. "weights", line 13, page 18. I, or page 20, line 1 and 2)
-- assigning the final count value the diagnostic prognosis using a predefined result table stored in the storage unit(page 28 line 2 and 3, line at 7 to 17).

The device of D2 does not use *lung function measurement data*.

The subject matter of claim 1 is therefore known from D2.

3. The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 2-18 does not involve an inventive step in the sense of Article 33(3) PCT, since none of the additional features of the 14 remaining dependent device claims appear to form the subject matter both new and inventive. The reasons are the following:

--claim 2 is unclear (Article 5 PCT) since the disease (COPD) to be diagnosed does not per se, define the device, more than by a result to be achieved, definition which is not allowed according to the Guidelines for examination at the EPO, CIII.4.7.
Hence, it does not modify the subject-matter of claim 1 which has been addressed in §2 above, further as far as the feature may be understood, it appears to be anticipated by D1 anyhow: cf. Paragraph 39*(COPD control score*), figure 10, line B, column 7, line 56 to line 57 and by D2 (cf. p. 5, l. 30).

-- the additional feature of claim 3 is also known from D1, cf. figure 9, line "grading".
-- the features of the remaining dependent claims 4 to 18 appear banal or well-known in the field or in the light of D1 or D2 and may not contribute to render the subject matter inventive.

Yves Bernas